

USSN 09/616,283; Attorney Docket No. VRXB-P01-001

CCY

In the claims:

1. (Currently amended) A method for screening for the presence of a clinically relevant amount of bacteria in donor blood or blood product from a healthy or asymptomatic donor mammal for transfer into a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of binding agents ~~span-generic antibodies~~, wherein the set of binding agents ~~antibodies~~ comprises binding agents ~~antibodies~~ that specifically bind to a Gram-negative bacterial antigen and binding agents ~~antibodies~~ that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents ~~antibodies~~ to the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of bacteria in the donor blood or blood product from the donor mammal, wherein the blood or blood product determined to have ~~an absence of a clinically relevant amount~~ less than  $1 \times 10^6$  colony forming units (CFU) per mL of bacteria is useful for transfer to the recipient mammal.
2. (Cancelled)
3. (Original) The method of claim 1, wherein the donor blood or blood product is selected from the group consisting of whole blood, leukocytes, hematopoietic stem cells, platelets, red blood cells, plasma, and serum.
4. (Currently amended) The method of claim 1, wherein the binding agents ~~antibodies~~ that specifically bind to the Gram-negative bacterial antigen specifically bind to the lipopolysaccharide structure of the Gram-negative bacteria.
5. (Currently amended) The method of claim 1, wherein the binding agents ~~antibodies~~ that specifically bind to the Gram-positive bacterial antigen specifically bind to the lipoteichoic acid structure of the Gram-positive bacteria.
6. (Currently amended) The method of claim 1, wherein the set of binding agents ~~antibodies~~ is immobilized on a solid-phase support.

USSN 09/616,283; Attorney Docket No. VRXB-P01-001

**COPY**

7. (Currently amended) A method for screening for the presence of a clinically relevant amount of Gram-positiv bacteria in donor blood product from a healthy or asymptomatic donor mammal for transfer into a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of binding-agentspan-generic antibodies, wherein the set of binding-agentsantibodies comprises binding-agentsantibodies that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding-agentsantibodies to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of Gram-positive bacteria in the donor blood or blood product, and wherein the donor blood or blood product from the donor mammal determined to have ~~an absence of a clinically relevant amount~~ less than  $1 \times 10^6$  CFU per mL of Gram-positive bacteria is useful for transfer to the recipient mammal.

8. (Currently amended) A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in donor blood product from a healthy or asymptomatic donor mammal for transfer to a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of binding-agentspan-generic antibodies, wherein the set of binding-agentsantibodies comprises binding-agentsantibodies that specifically bind to a Gram-negative bacterial antigen, detecting binding of the set of binding-agentsantibodies to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product, and wherein the donor ~~blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount~~ less than  $1 \times 10^6$  CFU per mL of Gram-negative bacteria is useful for transfer to the recipient mammal.

9-13. (Cancelled)

14. (Currently amended) A method for screening for the presence of a clinically relevant amount of bacteria in a donor tissue from a healthy or asymptomatic donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of binding-agentspan-generic antibodies, wherein the set of binding

USSN 09/616,283; Attorney Docket No. VRXB-P01-001

COPY

~~agents-antibodies~~ comprises ~~binding-agents-antibodies~~ that specifically bind to a Gram-negative bacterial antigen and ~~binding-agents-antibodies~~ that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of ~~binding-agents-antibodies~~ to the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of bacteria in the donor tissue, and wherein the donor blood or blood product from the donor mammal determined to have an ~~absence of a clinically relevant amount~~ less than  $1 \times 10^6$  CFU per mL of bacteria is useful for transfer to the recipient mammal.

15. (Previously presented) The method of claim 14, wherein the donor tissue determined to have an absence of a clinically relevant amount of bacteria is transferred to the second mammal.

16. (Original) The method of claim 14, wherein the donor tissue is selected from the group consisting of lung, heart, liver, skin, kidney, pancreas, spleen, and bone marrow.

17. (Currently amended) A method for screening for the presence of a clinically relevant amount of Gram-positive bacteria in a donor tissue from a healthy or asymptomatic donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of fluid with a set of ~~binding-agents~~ pan-generic antibodies, wherein the set of ~~binding-agents-antibodies~~ comprises ~~binding-agents-antibodies~~ that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of ~~binding-agents-antibodies~~ to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of Gram-positive bacteria in the donor tissue, and wherein the donor blood or blood product from the donor mammal determined to have ~~an absence of a clinically relevant amount~~ less than  $1 \times 10^6$  CFU per mL of Gram-positive bacteria is useful for transfer to the recipient mammal.

18. (Currently amended) A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in a donor tissue from a healthy or asymptomatic donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of ~~binding-agents~~ pan-generic antibodies,

USSN 09/616,283; Attorney Docket No. VRXB-P01-001

COPY

wherein the set of ~~binding agents~~antibodies comprises ~~binding agents~~antibodies that specifically bind to a Gram-negative bacterial antigen, detecting binding of the set of ~~binding agents~~antibodies to the Gram-negative bacterial antigen in the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of Gram-negative bacteria in the donor tissue, and wherein the donor tissue from the donor mammal determined to have ~~an absence of a clinically relevant amount~~less than  $1 \times 10^6$  CFU per mL of Gram-negative bacterial is useful for transfer to the recipient mammal.

19-25. (Cancelled)

26. (Currently amended) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the set of ~~binding agents~~antibodies are detectably labeled with a reporter molecule.

27. (Previously presented) The method of claim 26, wherein said reporter molecule is selected from the group consisting of a molecule with enzymatic activity, a radio-labeled molecule, a fusion molecule, a fluorogenic molecule, a metal sol, a particle, a chromatic molecule, or a molecule that is specifically bound by a secondary agent.

28. (Cancelled)

29. (Previously presented) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than  $1 \times 10^6$  CFU/ml of blood or blood product.

30. (Previously presented) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than  $1 \times 10^5$  CFU/ml of blood or blood product.

31. (Previously presented) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than  $1 \times 10^4$  CFU/ml of blood or blood product.

32. (Previously presented) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than  $1 \times 10^3$  CFU/ml of blood or blood product.

USSN 09/616,283; Attorney Docket No. VRXB-P01-001

33. (Previously presented) The method of claim 27, wherein the enzymatic molecule is selected from the group consisting of horseradish peroxidase, alkaline phosphatase, and  $\beta$ -galactosidase.
34. (Previously presented) The method of claim 26, wherein said reporter molecule is bound to the binding agent by intermolecular association.
35. (Previously presented) The method any of claims 1, 7, 8, 17, and 18 further comprising the step of transferring the blood or blood product to a recipient mammal.

COPY